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ORIGINAL RESEARCH: CLINICAL TRIAL

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An intervention including the national early warning score improves patient monitoring practice and reduces mortality: A cluster randomized controlled trial

Filip Haegdorens RN, MScN[1] | Koenraad G. Monsieurs MD, PhD[2] | Koen De Meester RN, PhD[1] | Peter Van Bogaert RN, PhD[1]

[1]Centre for Research and Innovation in Care (CRIC), Department of Nursing and Midwifery Sciences, University of Antwerp, Wilrijk, Belgium

[2]Department of Emergency Medicine, Antwerp University Hospital, University of Antwerp, Edegem, Belgium

Correspondence
Filip Haegdorens, Centre for Research and Innovation in Care (CRIC), Department of Nursing and Midwifery Sciences, University of Antwerp, Universiteitsplein 1, 2610 Wilrijk, Belgium.
Email: filip.haegdorens@uantwerp.be

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Abstract

Aims: To investigate the impact of the national early warning score on the frequency and the quality of vital sign registration and to study the association between protocol compliance and patient mortality.

Design: We conducted a post hoc data analysis of a stepped wedge cluster randomized controlled trial (RCT) in six hospitals.

Methods: All adult, non-pregnant patients admitted to 24 wards were included. The intervention comprised an observation protocol using the national early warning score combined with a pragmatic medical response strategy. Data collection lasted from October 2013–May 2015. Patient comorbidity scores and vital signs were sampled every 4 months on each ward. All vital signs in the 24 hr before a serious adverse event were collected.

Results: Patients (N = 60,956) were included of which 32,722 in the intervention group. Comorbidity scores were sampled in 3,600 patients and vital signs in 2,951 patients. In 668 patients, vital signs were collected before a serious adverse event. The mean number of vital signs per observation increased significantly in the intervention group. The observation frequency increased in patients with a serious adverse event and decreased in patients without a serious adverse event. Protocol compliance was negatively associated with patient mortality adjusted for comorbidity and age.

Conclusion: Our intervention improved patient monitoring practice and reduced mortality.

Impact: The impact of early warning scores on patient monitoring practice and patient outcomes remains unclear. Our intervention improved the observation of patients and reduced patient mortality. These results could support hospitals in their decision to implement rapid response systems.

Trial Registration: We have registered this study in the clinicaltrials.gov database (identifier: NCT01949025).

KEYWORDS

early warning score, mortality, nurses, protocol compliance, rapid response system, vital sign

1 | INTRODUCTION

Many unexpected deaths in acute hospitals are preceded by a long period of physiological instability that is often not recognized and inadequately managed by hospital staff (Findlay, Shotton, Kelly, & Mason, 2012). Problems associated with preventable deaths are most likely to occur on medical and surgical wards and involve poor clinical monitoring, diagnostic errors and a deficient response to clinical deterioration (Hogan et al., 2012). A system-based approach is needed for the detection and management of deteriorating patients. Timely recognition of deterioration and appropriate action may reduce morbidity and mortality. This fundamental idea led to the conceptual development of the Rapid Response System (RRS) which is an umbrella term for all system-based approaches aimed at detecting, interpreting and responding to deterioration (Lyons, Edelson, & Churpek, 2018). The aim of RRSs is to improve relevant patient outcomes. Two large randomized controlled trials, however, could not find a survival benefit in adults or children (Hillman et al., 2005; Parshuram et al., 2018). Only four studies investigated the effect of an RRS on nurses' clinical performance in vital sign registration of which three had a before and after design (Kyriacos, Jelsma, James, & Jordan, 2015; Meester, Haegdorens, et al., 2013; Mitchell et al., 2010; Paterson et al., 2006). Although these studies suggest a positive impact on the quality of the registration of vital signs, they had small sample sizes or were of limited methodological quality (Lee, Kim, Kim, & Oh, 2018).

1.1 | Background

In 31% of all in-hospital preventable deaths, deterioration was not detected because of poor clinical monitoring (Hogan et al., 2012). As a solution to this problem, physiological track and trigger scores were developed (Lee et al., 2018). These scores are designed to evaluate the patient's clinical status objectively and routinely by measuring vital signs and by comparing them with predefined reference ranges. It allows hospitals to use local resources effectively and to ensure that specialized staff is alerted in time if vital signs deviate (McNeill & Bryden, 2013). A variety of track and trigger scores are being used that can be categorized into single-, multiple-parameter, and aggregated weighted scoring systems (AWSS). The National Early Warning Score (NEWS) has a greater ability to discriminate adult patients at risk of cardiac arrest, unanticipated Intensive Care Unit (ICU) admission, or death within 24 hr of measurement compared with 33 other scoring systems (Smith, Prytherch, Meredith, Schmidt, & Featherstone, 2013). The NEWS is an AWSS developed and validated by the Royal College of Physicians (UK) using a large vital signs database (Royal College of Physicians, 2012). It was designed as an unambiguous and easy to use instrument with the aim to standardize the clinical assessment of adult, non-pregnant patients throughout the UK healthcare system (Royal College of Physicians, 2017). Although the NEWS is widely adopted today, the impact on the frequency and quality of vital sign registration and nurses' compliance to this intervention has never been studied in a large-scale multicentre randomized controlled trial (RCT). Hands et al. reported that the observation frequency proposed in the NEWS guideline, which is at least every 12 hr, is an unachievable routine in the current healthcare system (Hands et al., 2013). They attributed protocol non-compliance to increased workload, insufficient diagnostic equipment, and the limited face validity of RRS activation criteria. Furthermore, an association between compliance with the NEWS protocol and patient outcomes has never been proven (Lee et al., 2018). The current practice of observing patients and taking vital signs in hospitals is predominantly based on tradition and not on science (Mok, Wang, Cooper, Ang, & Liaw, 2015). A standard policy for observing hospitalized patients is needed to ensure consistency and quality. Traditionally, patients on general wards are monitored at fixed intervals in accordance with ward practices and doctor's orders. Nurses report that these practices are time-consuming and sometimes overwhelming, resulting in failure to collect complete and accurate vital signs. A patient-tailored monitoring approach should be used to determine the observation frequency which could theoretically improve patient monitoring practice and decrease workload (Storm-Versloot et al., 2014).

2 | THE STUDY

2.1 | Aims

The aim of this study was twofold: first, to investigate the impact of an RRS using the NEWS on the frequency and on the quality of the registration of vital signs, and second, to study the association between compliance with the NEWS protocol and patient mortality.

2.2 | Design

We conducted a post hoc analysis of data from a pragmatic, stepped wedge cluster RCT in Belgian acute hospitals from October 2013–May 2015. The general study design and block randomization method were explained extensively in a previous publication (including a CONSORT style flow diagram) (Haegdorens et al., 2018). This study lasted five periods of 4 months each (T0–T4) with phased introduction of the intervention.

2.3 | Sample

We initially included seven of 14 eligible acute hospitals in Belgium with two medical and two surgical wards each. One hospital did not collect data concerning patient's vital signs. Therefore, 24 wards in six hospitals were included in the current study. Acute care hospitals were eligible for participation in the study when they had at least two medical and two surgical wards with each at least 850 admissions per year, an ICU, a resuscitation team available 24/7, and no implemented RRS or EWS. All patients admitted to the participating wards in the study period were included. Patients were excluded if they were pregnant or younger than 17 years of age.

2.4 | Intervention

In the control group, standard care was provided where nurses observed patients according to local protocols or standard practice. Practices were generally tradition based and differed across wards, hospitals, and even between nurses. The intervention comprised the detection (afferent) and response (efferent) limb of an RRS. We introduced a standardized observation protocol based on the National Institute for Health and Care Excellence (NICE) guidelines using the NEWS combined with a pragmatic medical response strategy (Royal College of Physicians, 2012). Furthermore, we introduced a standard way of communicating using the Situation, Background, Assessment, and Recommendation (SBAR) method (De Meester, Verspuy, Monsieurs, & Van Bogaert, 2013). Hospitals integrated the NEWS in their own paper-based or electronic patient record. Nurses calculated the NEWS by using the patient's respiratory rate, oxygen saturation, supplemental oxygen administered, temperature, systolic blood pressure, heart rate, and level of consciousness (alert, verbal, pain, or unresponsive).

The baseline observation frequency for all hospitalized patients was one NEWS every 12 hr. Nurses were free to register extra observations if needed. According to the clinical risk category resulting from the NEWS (zero, low/green, medium/orange, high/red), the observation frequency had to increase or decrease in agreement with the NICE guidelines (Royal College of Physicians, 2012). Deviations from observation frequencies and call criteria were allowed on doctor's orders but had to be noted and signed in the patient record by the attending doctor.

The pragmatic and standardized medical response was nested in existing ward and hospital structures. We did not implement a rapid response team or medical emergency team (MET) in the study. The response strategy was tailored to the levels of clinical risk resulting from the NEWS.

The implementation of the intervention protocol was supported and organized by a designated project manager in each hospital. All project managers met on a monthly basis together with the researchers to discuss problems and to exchange ideas. This was also part of the strategy to ensure the homogeneity of the intervention between hospitals. Small adaptations to the medical response strategy were allowed to ensure adoption while avoiding a mismatch between the intervention and the ward's unique characteristics. No changes were allowed in the calculation of the NEWS or in the observation frequency.

One week before the start of the intervention ward nurses received an interactive training session concerning the measurement and interpretation of vital signs, clinical observation, communication skills, and practical tips and tricks about NEWS and SBAR. The trainers (FH and MM) were experienced practicing nurses. It was emphasized that the goal of our intervention was certainly not to increase the nurses' workload, but instead to shift time to care from stable to deteriorating patients. During this training, we also explained that this project was supported by the hospital management, therefore acknowledging the problems the nursing staff had experienced with deteriorating patients. The mandatory training lasted 4 hours and was based on the innovation–decision theory by Rogers to maximize adoption (Rogers, 1995).

2.5 | Data collection

Data were collected between October 2013 and May 2015. We collected: (a) patient outcomes (unexpected death, cardiac arrest with CPR, and unplanned ICU admission); (b) patient characteristics (gender, age, and length of stay); (c) patient comorbidity scores; and (d) clinical monitoring data (registered vital signs). All primary patient outcomes are defined in our first publication (Haegdorens et al., 2018). The combined mortality rate was a composite outcome composed of unexpected death and death within 72 hr after cardiac arrest with CPR or unplanned admission to the ICU. Patient comorbidity was measured using the Charlson comorbidity index (CCI) and collected from 30 consecutive patient admissions across all wards starting on the last Monday of the second month of each period (T0–T4).

Clinical monitoring data comprised two datasets: a cross-sectional sample and an SAE sample. The cross-sectional sample included all registered vital signs and NEWS values of admitted patients to the study wards in a 24-hr timeframe on a randomly chosen Tuesday in the second month of each period (T0–T4). Patients experiencing a Serious Adverse Event (SAE; unexpected death, cardiac arrest with CPR, and unplanned ICU admission) were excluded from this first sample. The SAE sample included all registered vital signs and NEWS values collected in a 24-hr period before the actual event in all patients experiencing a SAE throughout the study.

Nurse protocol compliance was calculated for all patients in the cross-sectional sample in the intervention group. Protocol compliance was defined as a registered NEWS at least every 12 hr including all six vital signs and supplemental oxygen per patient.

2.6 | Validity and reliability

The computerized randomization procedure was performed by a statistician who was not involved in the further conduct of the study. The hospital management was blinded for the intervention date on their wards until 1 month before inclusion in the intervention group. The ward staff were only informed of their inclusion in the study 2 weeks before the intervention started.

An extensive patient record review was performed to determine the primary outcomes. We reviewed each patient record in case of a crude outcome indicator (crude mortality, resuscitation team calls, and all transfers to the ICU). We used a standardized electronic checklist to collect data. Outcome indicator definitions were matched against patient records. In case of uncertainty, the patient record was reviewed and discussed by two independent researchers to achieve agreement.

2.7 | Ethical considerations

Approval of the ethics committee of Antwerp University Hospital and of the ethics committees of all local hospitals was obtained before the start of the study (registration number: B300201317835).

2.8 | Data analysis

All data were analysed using IBM SPSS Statistics version 24 for MAC OS. Patient outcome measures were presented per 1,000 patient admissions. Continuous data were tested for normality using the absolute skewness (≤2) and kurtosis (≤7) for sample sizes greater than 300, using z-scores (between −3.29 - 3.29) for sample sizes between 50 and 300 or using z-scores (between −1.96 and 1.96) for sample sizes smaller than 50 (Kim, 2013). In case of a non-normal distribution, we chose an appropriate non-parametric test. All proportions between two or more groups were tested with the Pearson's Chi-squared test. When studying correlations between protocol compliance, age, gender, comorbidity, and patient outcomes, we aggregated our database to the ward level (*N* = 24) and included only data from the intervention group. The percentage of patients with protocol compliance, mean age, percentage males, mean CCI, unplanned ICU admission rate, cardiac arrest rate, unexpected death rate, and combined mortality rate were calculated for each ward in the intervention group. We used Pearson product-moment correlation coefficients if all included variables had a normal distribution. To study the impact of a ward's mean CCI, we categorized all mean ward CCIs in quartiles. Using a univariate linear regression analysis, we studied the association between protocol compliance and the combined mortality rate in the intervention group per CCI quartile. Subsequently, we also used a multiple linear regression analysis while controlling for the mean CCI and mean age.

3 | RESULTS

Six hospitals with each four wards (*N* = 24) were included in this study. We included 60,956 patient admissions from October 2013–May 2015 accounting for 303,559 patient days. The intervention group contained 32,722 patient admissions. CCI's were collected in 3,600 patients spread over all 24 wards of which 1740 in the control group. The cross-sectional sample comprised 2,951 patients of which 1,361 in the control group (Table 1). The SAE sample comprised 668 patients of which 266 in the control group.

3.1 | Analyses comparing the control and intervention group

Patient and sample characteristics were compared between the control and intervention groups in Table 1. In both samples, patients in the intervention group (cases) were younger compared with the control group (controls). In the cross-sectional sample, the length of stay (LOS) was significantly shorter in the intervention group. We found an increase of LOS in patients experiencing a SAE in the intervention group. In the cross-sectional sample, 4.6% of all patients did not have a single registered observation and 3.0% patients experiencing an SAE had no observations before the event. We found no statistical difference in the percentage of patients without observation comparing the control and intervention group in both samples.

In Figure 1, we compared the percentages of registered vital signs between the control and the intervention groups in both samples. In the cross-sectional sample of the control group (Figure 1a), the blood pressure was the most registered vital sign, while the patient's consciousness was only measured in 1% of all observations. The most registered vital sign in the cross-sectional sample of the intervention group was the temperature, while the administered oxygen was the least registered parameter.

In the SAE sample of the control group (Figure 1b), the heart rate was the most registered vital sign, while the patient's

TABLE 1 Comparison of patient and sample characteristics between the control and intervention group in the cross-sectional and serious adverse event sample

	Cross-sectional sample (*N* = 2,951)		Up to 24 hr before SAE (*N* = 668)	
	Controls (*N* = 1,361)	Cases (*N* = 1590)	Controls (*N* = 266)	Cases (*N* = 402)
Patient characteristics				
Males (%)	51.3	51.2	57.0	53.4
Age (mean years, *SD*)	64.6 (16.6)	63.6 (16.9)	72.3 (14.4)	69.7 (14.5)*
LOS ward (mean days, *SD*)	12.5 (14.9)	9.7 (11.3)**	10.8 (13.8)	12.1 (13.2)*
LOS hospital (mean days, *SD*)	14.1 (17.3)	11.2 (14.4)**	20.1 (23.7)	17.9 (14.3)
Sample characteristics				
Patients without observations (%)	5.2	4.1	3.0	3.0
Total number of observations (*n*)	3,472	4,178	1,192	2,020

Note: Proportions: Pearson's Chi-Squared test. Age, LOS: Mann–Whitney *U* test.
Abbreviations: LOS, Length of Stay in days; h, hours; SAE, Serious Adverse Event.
*$p < 0.05$ (comparing cases with controls).
**$p < 0.001$ (comparing cases with controls).

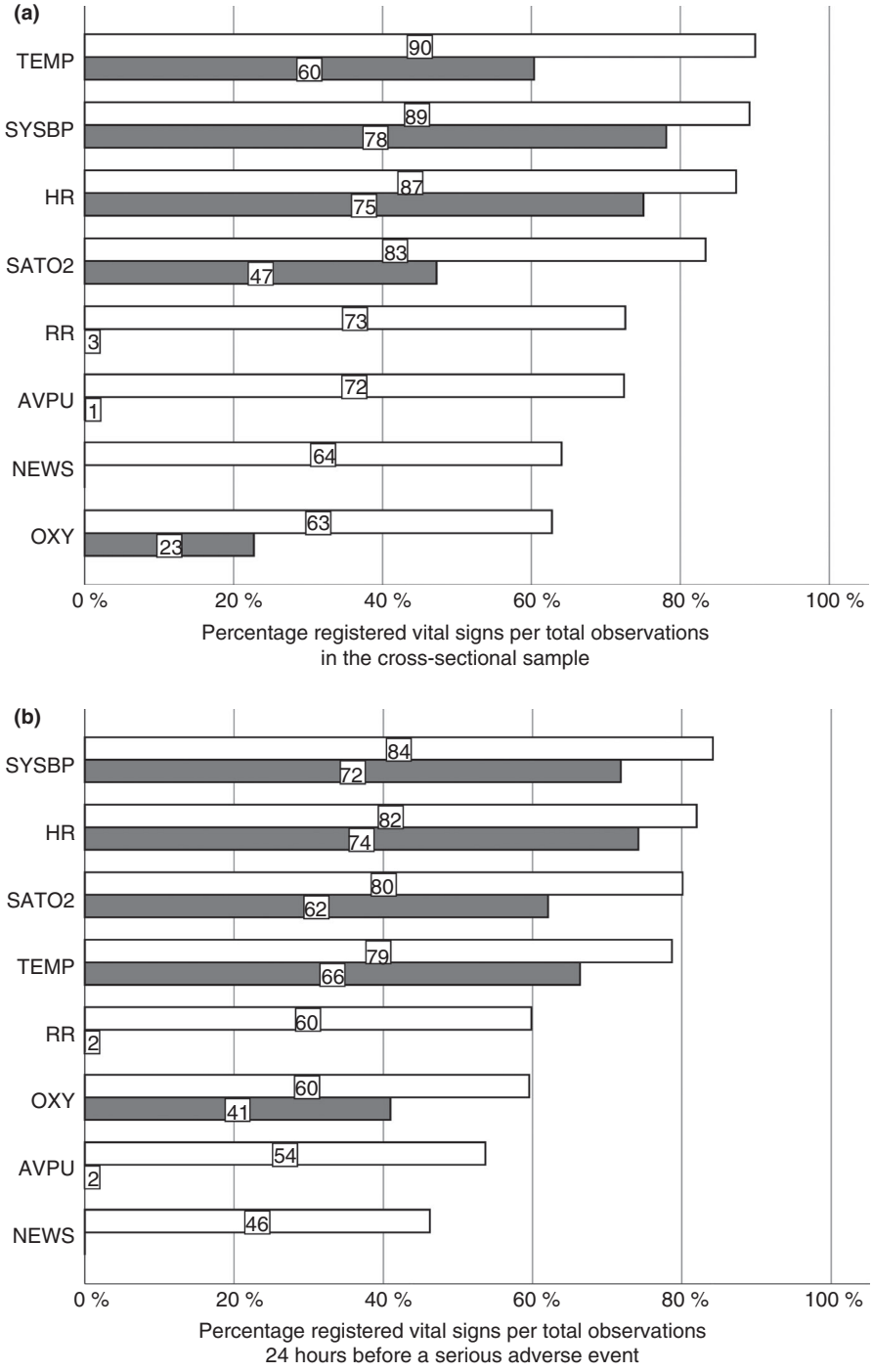

FIGURE 1 Percentage registered vital signs per total observations in the control group vs. the intervention group. (a) Registered vital signs in the cross-sectional sample. Cases (N = 4,178) vs. controls (N = 3,472), $p < 0.001$ (Pearson's Chi-Squared test). (b) Registered vital signs in the events sample. Cases (N = 2020) vs. controls (N = 1,192), $p < 0.001$ (Pearson's Chi-Squared test). White bars indicate cases and grey bars indicate controls. TEMP: temperature, SYSBP: systolic blood pressure, HR: heart rate, SATO2: oxygen saturation, RR: respiratory rate, AVPU: patient's consciousness, NEWS: national early warning score, OXY: supplemental oxygen.

consciousness and respiratory rate were only measured in 2% of all observations. The most registered vital sign in the SAE sample of the intervention group was the blood pressure, while the patient's consciousness was the least registered parameter. The NEWS was registered in 64% of all observations in the cross-sectional sample of the intervention group. In the 24 hr before an SAE, we found a registration of the NEWS in 54% of all observations. All vital signs were measured more frequently in the intervention group of both samples.

Table 2 compares the observation frequency expressed in mean number of hours between two observations and mean number of vital signs per observation between controls and cases for the two samples. In the cross-sectional sample, we found an increase of the mean number of hours between observations in the intervention group vs. the control group. This can be interpreted as a decrease of the observation frequency. Contrastingly, in the SAE sample, we found a decrease of the mean number of hours between observations in the intervention group vs. the control group. Thus, patients experiencing an SAE were more frequently observed in the intervention group. The mean number of vital signs per observation increased significantly in both samples.

TABLE 2 Comparison of the observation frequency and the mean number of vital signs between the control and intervention group in the cross-sectional and serious adverse event sample

		Controls	Cases	Difference
Hours between two observations[a]	x	5.58 (2.70) *N* = 1,000	6.14 (2.98) *N* = 1,221	+0.56[c]
	e	6.33 (4.61) *N* = 232	4.65 (3.11) *N* = 361	−1.68[c]
Number of vital signs per observation[b]	x	3.07 (1.16) *N* = 1,314	5.77 (1.34) *N* = 1556	+2.70[c]
	e	3.35 (0.99) *N* = 257	5.15 (1.51) *N* = 388	+1.80[c]

Note: x: cross-sectional sample, e: up to 24 hr before serious adverse event.
[a]Mean (*SD*) number of hours between two observations.
[b]Mean (*SD*) number of vital signs per observation.
[c]Significant differences at the 0.001 level (independent *t* test).

TABLE 3 Significant correlations between protocol compliance, age, comorbidity, and patient outcomes in the intervention group

		A	B	C	D	E	F	G
A	Protocol compliance (%)							
B	Unplanned ICU admission rate	0.007						
C	Cardiac arrest rate	−0.084	0.469[b]					
D	Unexpected death rate	−0.451[b]	0.036	0.417[b]				
E	Combined mortality rate	−0.364[a]	0.562[c]	0.729[c]	0.694[c]			
F	Age (mean)	0.129	0.353[a]	0.506[b]	0.081	0.483[b]		
G	Males (%)	0.544[c]	0.206	0.198	−0.200	0.038	0.444[b]	
H	CCI (mean)	0.419[b]	0.690[c]	0.149	−0.160	0.309	0.421[b]	0.588[c]

Note: Pearson product-moment correlation coefficients (*n* = 24 wards).
Abbreviations: ICU, Intensive Care Unit; B–E, mean rates per 1,000 admissions; CCI, Charlson comorbidity Index.
[a]Significant at the 0.10 level.
[b]Significant at the 0.05 level.
[c]Significant at the 0.01 level.

3.2 | Analyses of the intervention group data

In the cross-sectional sample of the intervention group, 47.7% of all patients (*N* = 1590) were observed in agreement with the NEWS protocol (protocol compliance). In the total intervention group, 51.5% of all patients (*N* = 32,722) were men and the average age was 60.5 years (*SD* 18.0). The mean CCI in the intervention group was 1.58 (*SD* 1.07). Furthermore, the unplanned ICU admission rate was 10.7 per 1,000 admissions, the cardiac arrest rate was 1.0 per 1,000 admissions, and the unexpected death rate was 0.6 per 1,000 admissions. In 0.9 per 1,000 admissions, the patient died within 72 hr after an unplanned admission to the ICU. In 0.6 per 1,000 admissions, a patient died within 72 hr after a cardiac arrest with CPR. The combined mortality rate, which was composed of unexpected death, death within 72 hr after an unplanned ICU admission or following cardiac arrest with CPR, was 2.1 per 1,000 admissions.

In the analysis in Table 3, we aggregated all data to the ward level (*N* = 24) and calculated correlation coefficients between all shown variables in the intervention group. The percentage protocol compliance showed a weak negative association with the combined mortality rate ($r = -0.364$, $p = 0.080$), a moderate negative association with the unexpected death rate ($r = -0.451$, $p = 0.027$), a moderate positive association with the mean CCI ($r = 0.419$, $p = 0.042$), and a moderate positive association with the percentage of males ($r = 0.544$, $p = 0.006$).

In a univariate linear regression analysis, we studied the association between protocol compliance and the combined mortality rate per 1,000 admissions in the intervention group per CCI quartile (Figure 2). The first CCI quartile ranged from 0.23-0.60, the second from 0.70-1.14, the third from 1.24-2.35, and the fourth from 2.37-3.86. Four regression lines are shown in Figure 2, one for each CCI quartile. In the first and second CCI quartiles, we found no significant association between the protocol compliance and the combined mortality rate. In CCI quartile three, the association was statistically significant considering an α of 0.100 with an adjusted R^2 of 38%. Lastly, in CCI quartile four, the association was statistically significant considering an α of 0.05 with an adjusted R^2 of 86%.

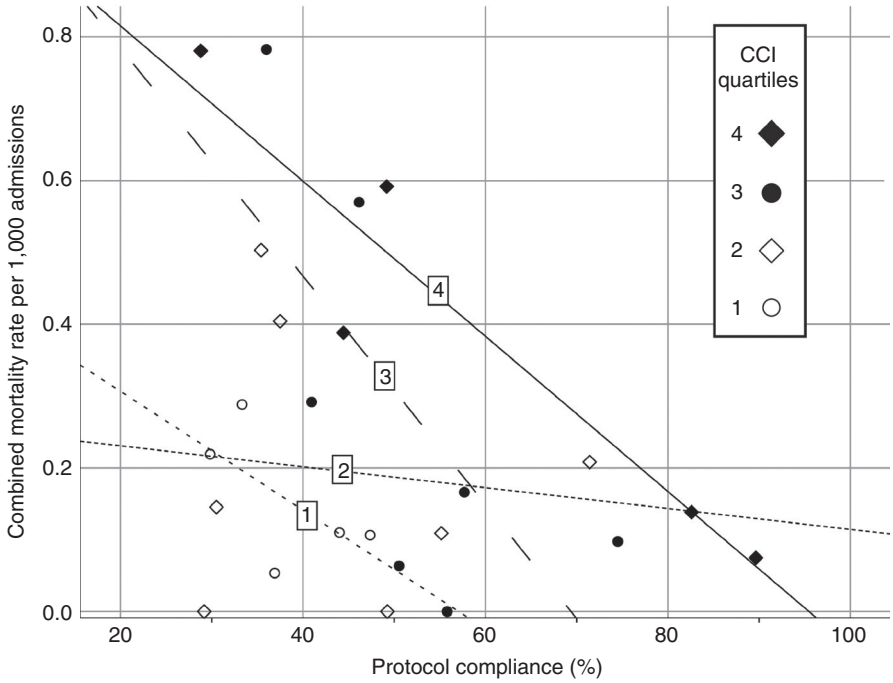

FIGURE 2 Scatterplot showing the effect of protocol compliance on the combined mortality rate in the intervention group. n = 24 wards. Univariate linear regression analysis per CCI quartile. 1: adj. R^2 20%—p > 0.100, 2: adj. R^2 18%—p > 0.100, 3: adj. R^2 38%—p = 0.084, 4: adj. R^2 86%—p = 0.016. CCI: Charlson comorbidity index, combined mortality: composite outcome of unexpected death and death within 72 hr after cardiac arrest with CPR or unplanned admission to the ICU, adj. R^2: adjusted R-squared

In Table 4, a multiple linear regression analysis shows the association between the percentage protocol compliance and the combined mortality rate per 1,000 admissions adjusted for the mean CCI and the mean age in each ward (N = 24). The variance in the combined mortality rate is explained for 45% by this model. When male gender was added to this model the coefficient of determination did not change significantly and the association between independent and dependent variables remained the same, therefore this variable was omitted from the model. We found a significant negative association between the percentage protocol compliance and the combined mortality rate per 1,000 admissions adjusted for the CCI and the age.

4 | DISCUSSION

In this study, we have shown that our intervention resulted in an increase of the registration of all six vital signs and supplemented oxygen. Furthermore, we found a reduction of the observation frequency in clinically stable patients and an increase of the observation frequency in deteriorating patients. These results were anticipated and in accordance with the training we supplied but somewhat contradictory when compared with previous research. In two recent systematic reviews concerning the effect of Early Warning Scores on the clinical performance of nurses, the authors concluded that the recording of vital signs improved after implementing EWSs (Lee et al., 2018; Saab et al.., 2017). In most studies, an increase in the number of vital signs registered per observation was found which corresponded with our results. However, in the only two studies investigating EWSs where observation frequency was measured, patients were more frequently observed after the intervention (Meester, Haegdorens, et al., 2013) (Mitchell et al., 2010). Different versions of the Modified Early Warning Score (MEWS) were used in these studies, which is an older, more complex and less validated EWS compared with the NEWS. The decrease in observation frequency in our study could be explained by our emphasis during the nurses' training sessions on shifting time to care from stable to deteriorating patients.

Our second aim was to study the possible association between compliance with the NEWS protocol and patient outcomes. The MERIT study, an RCT in 23 Australian hospitals, studied the effect of an MET on patient outcomes but was inconclusive (Hillman et al., 2005). In a post hoc analysis, a negative dose–response relationship between MET calling rates and patient outcomes was found

TABLE 4 Multiple linear regression analysis showing the association between protocol compliance and the combined mortality rate per 1,000 admissions adjusted for comorbidity and age in the intervention group

		95% CI for B			
Variables	**Unstandardized B**	**Lower**	**Upper**	**Standardized β**	***p***
Protocol compliance	−0.081	−0.131	−0.031	−0.576	0.003
Comorbidity	0.894	−0.016	1.805	0.383	0.054
Age	0.192	0.019	0.364	0.396	0.031

Note: N = 24 wards, p-model: 0.002, adjusted R-Squared: 45%. Protocol compliance: percentage, comorbidity: mean Charlson comorbidity Index, age: mean age.

(Chen, Bellomo, Flabouris, Hillman, & Finfer, 2009). However, MET calling criteria were only based on deviations of a single vital sign. Moreover, to call a MET, deterioration must be effectively and efficiently detected beforehand. Our current study is, to our knowledge, the only study confirming a dose–response relationship between NEWS protocol compliance and patient outcomes. Moreover, reductions in mortality have been found in most studies investigating RRSs but they may have been biased by shifting risk without truly providing "rescue" (i.e., ward deaths are avoided by moving patients to the ICU) (Lyons et al., 2018). We found a significant negative association between compliance with the NEWS protocol and unexpected death including failure to rescue after a serious adverse event (death after cardiac arrest or death after an unplanned admission to the ICU). This result remained valid after adjusting for patient comorbidity and age. Consequently, this could imply that the detection of deterioration using NEWS is a key part in the conceptual framework of an RRS. To achieve maximal adoption in this study, we used a pragmatic medical response strategy and a training programme for nurses which could be imperative to adequate RRS performance. Given the significant cost of an RRS and the impact it has on the nurses' work environment, any implementation of an RRS should be well thought out (Jensen, Skår, & Tveit, 2018). We found that only wards in the two highest comorbidity quartiles possibly benefitted from adhering to our protocol. This may imply that wards admitting patients with low comorbidity scores (e.g., day surgery or the maternity ward) may benefit less from implementing an RRS.

4.1 | Limitations

The most important limitation of this study was that it comprises a post hoc analysis of data collected for another study. Therefore, it was not possible to prove causal relationships. This study included a large sample of hospitalized surgical and medical patients admitted to Belgian hospitals. An aggregated database was generated providing estimations of patients' vital sign measures, age, and comorbidity per study ward. No linked data concerning these measures were available on the patient level. Therefore, no statements could be made about individual patients. Another limitation was that we used the CCI as a risk adjustment measure which has a lower predictive ability for mortality compared with other scores (Needham, Scales, Laupacis, & Pronovost, 2015). However, the CCI requires less data to calculate which makes it a feasible method for risk adjustment in healthcare research.

5 | CONCLUSION

Implementation of an RRS including NEWS improves nurses' performance in observing patients without increasing workload in clinically stable patients. Furthermore, compliance with the NEWS protocol was negatively associated with unexpected death (including failure to rescue after a serious adverse event) adjusted for age and comorbidity. An RRS including NEWS is an efficient and effective method to detect and manage clinically unstable patients on the general ward. Sufficient evidence is available to support adoption of this intervention on medical and surgical wards in acute hospitals.

CONFLICT OF INTEREST

The authors received a grant from the Federal Public Service of Health, Food chain safety, and Environment of Belgium for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; PVB is co-author of an ongoing update of a Cochrane systematic review with the following title: "Outreach and EWS for the prevention of ICU admission and death of critically ill adult patients on general hospital wards".

AUTHORS CONTRIBUTION

FH, KM, KDM, and PVB made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; FH, KM, and PVB involved in drafting the manuscript or revising it critically for important intellectual content; FH, KM, KDM, and PVB given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; FH agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

ORCID

Filip Haegdorens https://orcid.org/0000-0003-1996-8786

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